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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
09/810,872	03/16/2001	Peter Zhu	JOHNA 058A	7471

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EXAMINER	
CROSS, LATOYA I	
ART UNIT	**PAPER NUMBER**
1743	

DATE MAILED: 02/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Application No.	Applicant(s)	
09/810,872	ZHU ET AL	
Examiner	**Art Unit**	
LaToya I. Cross	1743	

Office Action Summary

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,10-23 and 25-33* is/are pending in the application.

4a) Of the above claim(s) *15-23,25-29 and 31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,10-14,30,32 and 33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 1, 2003 has been entered. Claims 1-7, 10-23 and 25-33 are currently pending. Claims 15-23, 25-29, and 31 are withdrawn from consideration as being directed to non-elected subject matter.

Claim Observations

- Claim 10 states that first reaction produces a second color. The Examiner presumes, from the specification, that this second color is "colorless". The phrase is unclear, however, because Applicants refer to a first color in the context of the second reaction (claim 1), and a second color in the context of the first reaction (claim 10). It would be clearer if the first color denotes the produce of the first reaction and the second color denotes the produce of the second reaction.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action.

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States

3. Claims 1-7, 10-12, 14 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 4,471,055 to Opp.

Opp teaches a process for determining whether the concentration of aldehyde in a sample is in excess of a predetermined concentration. The predetermined concentration of aldehyde is the point of interest of aldehyde. The method for determining whether aldehyde is present in a predetermined concentration taught by Opp comprises mixing the test sample with a first reaction system which reacts with carbonyl group in aldehydes, followed by reaction of the resultant product with a second reaction system, which reacts with any unreacted aldehyde, and detecting any visual formation of a second reaction product, as recited in claim 1 (col. 14, lines 7-41). With respect to Applicants' claimed limitation of the first reaction step occurring in the presence of the second reactant, Opp teaches at col. 3, lines 17-24 that the two reaction systems can be combined simultaneously with the sample at the beginning of the assay. The aldehydes to be tested are those used in disinfecting systems (in germicidal capacities) having at least one –CHO moiety, which includes glutaraldehyde, as recited in claims 6 and 7. The first reaction system includes reactants which form a colorless derivative of aldehyde, such as hydroxylamine or hydrazine, as recited in claim 5 (col. 4, lines 15-30). The second reaction system includes reactants that form aldehyde derivatives which are visually distinguishable from the first reaction products, such as amino acids, including glycine and lysine, as recited in claims 2-4 (col. 4, lines 38-55). Opp teaches that the first reaction products are colorless, as recited in claim 10 (col. 4, lines 15-17, col. 14, lines 42-43). With respect to claim 11, Opp teaches that the amount of first reaction system completely transform the amount of aldehyde equal to the predetermined amount, while the second reaction system provides a visual color where the amount of aldehyde exceeds the predetermined amount. Where the amount of

aldehyde is less than the predetermined amount (1% for disinfecting processes), it would be inherent that no color would form since there would not be an excess amount of aldehyde to react in the second reaction system. With respect to claim 12, each of examples I-IX of Opp teaches providing a fixed volume of sample (0.1-1 milliliter) to which the reactants are added. Further, with respect to claim 14, Opp teaches that the fixed volume of test sample is added to a 7 cc reaction container (measuring device), where the reaction container contains the first reaction system reagents (hydroxylamine or hydrazine).

Therefore, for the reasons set forth above, Applicants' claimed invention is deemed to be anticipated, within the meaning of 35 USC 102(b) in view of the teachings of Opp '055.

Claim Rejections - 35 USC § 103

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Opp in view of US Patent 4,703,763 to McAlister et al.

The disclosure of Opp is described above. Opp fails to teach loading a fixed volume of test sample into a measuring device having a liquid impermeable membrane.

McAlister et al teach a device for sample a pre-set volume of test sample. The device is a syringe-type measuring device having a plug element (filter) arranged to be air-permeable, but liquid impermeable. This allows enough fluid sample to be up taken into the syringe and then allow the fluid flow to stop when the predetermined amount is taken in. See col. 1,lines 41-59. It would have been obvious to one of ordinary skill in the art to use the device of McAlister et al to measuring an exact amount of test sample in carrying out the method of

Opp. Such will prevent using excess sample. Since it is important that the amount of reagents in the method of Opp be exact for the amount of sample, using the device of McAlister et al will alleviate false positives due to incorrect reagent to sample ratios.

Therefore, for the reason set forth above, Applicants' claimed invention is deemed to be obvious, within the meaning of 35 USC 103, in view of the teachings of Opp and McAlister et al.

6. Claims 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Witonsky in view of Wu.

Witonsky et al teach a method for determining whether the concentration of disinfectant/sterilant exceeds a predetermined value. The method tests for sufficient glutaraldehyde amounts in a disinfecting solution using test strips (CIDEX OPA tests for phthalaldehdye). The method involves contacting a test sample with a test strip impregnated with a sulfite compound and an amino acid compound. The sulfite compound is sodium sulfite (col. 2, line 24). The amino acid is glycine (col. 2, line 27). The method by which excess glutaraldehyde is to be determined is explained in Wu. Glutaraldehyde reacts with sulfite to form a sulfite addition product, which reacts with glycine to form sodium glycinate. Excess glutaraldehyde reacts with sodium glycinate to form a colored product. Thus, the sulfite serves as a first reactant to react with the carbonyl group in the aldehyde and sodium glycinate serves as the second reactant to react with remaining aldehyde in the sample that is unreacted. See col. 2, lines 39-52 of Wu.

Witonsky et al teaches using sodium sulfite, but fail to teach using sodium bisulfite. Wu teaches that both sodium sulfite and sodium bisulfite are effective in processes for determining

the presence of aldehydes (col. 1, line 65 – col. 2, line 12). It would have been obvious to one of ordinary skill in the art to substitute sodium sulfite in Witonsky et al for sodium bisulfite, since both are known in the art to be suitable in determining the presence of aldehydes. See MPEP 2144.06.

With respect to claim 33, where Applicants recite that the first reaction step is kinetically and thermodynamically favored over the first second reaction step, such would have been obvious to the ordinarily skilled artisan because Wu teaches that aldehyde in the sample reacts with the sulfite first prior to reacting with glycine. Thus, the first reaction step would obviously have to be favored over the second reaction step.

Therefore, for the reasons set forth above, Applicants' claimed invention is deemed to be obvious, within the meaning of 35 USC 103, in view of the teachings of Witonsky et al and Wu.

Response to Arguments

7. Applicant's arguments filed December 1, 2003 have been fully considered but they are not persuasive. With respect to the anticipatory rejection over Opp, Applicants argue that Opp fails to teach having the first reactant perform its reaction in the presence of the second reactant. The Examiner disagrees. At col. 2, lines 24-32, Opp teaches that

> "the first reaction system and the second reaction system are characterized in that, when both are combined with the predetermined quantity of sample, the first reaction system is capable of transforming completely to the first reaction product essentially the amount of aldehyde which is equal to the predetermined minimum concentration before the second reaction product is visually detectable."

Opp further teaches at col. 3, lines 19-24

> "If the reaction kinetics of the two reaction systems are such that the first reaction system acts first and goes to completion before the second reaction system has acted to any significant extent, the two reaction systems may be combined simultaneously with the sample at the beginning of the assay."

Thus, Opp clearly teaches a method where the first reaction occurs in the presence of the second reactant. Applicants have pointed out that Opp teaches delaying the dissolution of the second reactant; however, this is a different embodiment for where the reaction rates are the same.

With respect to the rejection over Opp in view of McAlister, Applicants argue that there is no suggestion for using the combination. As stated in the rejection, the device of McAlister allows the user to take up a set amount of sample, preventing any waste and preventing the possibility of false positives due to the use of incorrect amounts of reagents. The ordinarily skilled artisan would have recognized that syringes are not only used in drawing blood; they are in fact used in a variety of capacities including in assaying.

With respect to the rejection over Witonsky in view of Wu, Applicants argue that Wu teaches that the glycine reacts with the reaction product. This was a misstatement. The Examiner meant to point out sodium glycinate (an amino acid salt) reacts with excess aldehyde to produce a detectable color.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya I. Cross whose telephone number is 571-272-1256. The examiner can normally be reached on Monday-Friday 8:30 a.m. - 5.00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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February 19, 2004

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